UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,563	09/26/2003	Gerhardt Kumpe	06478.1494	8137

22852 7590 11/16/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,563	KUMPE ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13, 15, and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Final office action is in response to the paper filed on 08/24/2007

Status of Claims

Claims 1-24 are pending. Claims 1-9 and 16-18 are withdrawn. Claims 10-13, 15, and 19-24 are pending and are currently under examination.

Rejection Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 15, and 19-24 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

1.) The nature of the invention: The claimed invention is drawn to a method for producing a concentrate of factor VIII:C containing vWF comprising fractional precipitation using an alkali metal salt and an amino acid glycine, for example, wherein

the concentrate has high molecular weight multimers of vWF and the ratio of ristocetin cofactor to vWF is greater than 1.

2.) The breadth of the claims: the claims are broad because they refer to a process for producing a concentrate of factor VIII:C-containing von Willebrand factor (vWF/FVIII:C) wherein the concentrate has a ratio of vWF:RcoF to vWFAg of greater than 1.

3.) The predictability or unpredictability of the art: / 7.) The state of the prior art: The prior art, Heimburger et al., Factor VIII Concentrate, Highly-Purified and Heated in Solution, Drug Res. 31(I), Nr. 4 (1981) (See original German article and the English translation of the article as attached to this office action), teaches a method that is the same as the instant method wherein a solution is fractionally precipitated using sodium chloride and glycine. See page 3, and Table 1, on page 7, of the English translation. Table 2, of the English translation depicts composition of the factor VIII concentrates and comparison to a commercial product, where the ratio of ristocetin to vWF is less than 1. See calculation where values were used from Table 2, page 11 of the English translation: FVIII:RcoF=23.6; FVIIIR:Ag/FVIII:C=3; FVIII:C=25; thus FVIIIR:Ag=75 thus FVIII:RcoF/FVIII R:Ag=23.6/75=0.314 thus less than 1.

Therefore, the instant invention is unpredictable because the instant method claimed does not produce a concentrate in which the ratio of ristocetin to vWF is greater than 1 because the prior art reference teaches that the same method steps produce a concentrate in which the ratio is less than 1. Thus, according to the method instantly

claimed, it appears that steps to produce a concentrate of ristocetin to vWF greater than 1 are not claimed.

4.) & 5.) The amount of direction or guidance presented:/The presence or absence of working examples: the working examples 1 and 2 and Table 1 on pages 10 and 11, present calculations that a concentrate of ristocetin to vWF is greater than 1.

6.) The quantity of experimentation necessary: there is a large quantity of experimentation necessary to determine whether the method claimed, i.e. a process for producing a concentrate of a vWF/FVIII:C where the concentrate has a ratio of vWF:RcoF to vWF:Ag that is greater than 1, is actually claimed since the prior art by Heimburger et al. clearly teaches the same method that utilizes the same steps where the ratio for the same compositions is less than 1.

8.) Level of skill in the art: the level of skill in this art is high.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Applicants responded to the rejection by stating that on page 3 of the last office, examiner referred to fractional precipitation with aluminum hydroxide that is not a salt. However, Applicants also pointed out that Heimburger teaches precipitation of factor vWF/FVII:C with sodium chloride, which is an alkali metal salt. See also, Heimburger on

page 6 of the translation document, as submitted to the Applicants by examiner in the last office action.

Further, Applicants argue that in Heimburger, failure to produce vWF/FVIII:C concentrate in which the ratio of vWF:RcoF to vWF:Ag is greater than 1 does not reflect nonenablement of the claimed invention. Further, Applicants point out the holding in *Atlas Powder* that the patent was enabling despite any inoperable embodiments because the provided sufficient guidance such that one skilled in the art could determine the proper combination of ingredients to limit the claims to operative embodiments. Further, Applicants present operable embodiments encompassed by claims 10-13, 15, and 19-24, see example on page 8 lines 6-16 and page 14 lines 29-31. In conclusion, Applicants stated that ample guidance is provided by the specification to readily identify operable embodiments of the instantly claimed invention without undue experimentation.

Examiner acknowledges the Applicants arguments, however the rejection is maintained. First, examiner would like to point out that Heimburger and the instant invention discusses the same process for producing a concentrate that utilizes the exactly same steps, thus the end product should be identical.

In re Sussman, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), provides "that since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." In the instant case, the claims are drawn to an invention employing the **same process steps** but the product(s) is(are) **alleged to be different**.

Analogously, Heimburger teaches a process of producing concentrate of a factor VIII:C-containing von Willebrand factor (vWF/FVIII:C) when a liquid having factor VIII:C (FVIII:C) and von Willebrand factor (vWF) is fractionally precipitated using at least one of an alkali metal salt and an amino acid glycine. Further, the dissolved precipitate is incubated for 10 hrs at 60°C. See Heimburger on page 6 of the translation.

Identically, in the instant invention, the concentrate of the invention is preferably obtained by fractional precipitation using glycine and an alkali metal salt such as sodium chloride. See example 1 on page 9. Further, the dissolved precipitate is incubated for 10 hrs at 60°C, for example.

Therefore the steps in achieving the concentrate are the same, thus the ratios should be the same.

Applicants claimed that the concentrate has a ratio of von Willebrand factor ristocetin cofactor activity (VWF:RcoF) to von Willebrand factor antigen (VWF:Ag) of greater than 1. Heimburger discloses a ratio of less than 1 (specifically the value of 0.314).

Therefore, according to *In re Sussman*, since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims. In the instant case, the claims are drawn to an invention employing the same process steps but the products, i.e. ratios, are allegedly to be different. Thus, Applicants are required to recite the missing steps to form the alleged different ratios in view of the above-cited decision.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have

any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER